



Medical Necessity Criteria for Targeted Immunomodulatory Biologics

Drug Class – Targeted Immunomodulatory Biologics (TIBs). This drug class includes Humira (adalimumab), Amevive (alefacept), Raptiva (efalizumab), Enbrel (etanercept), Kineret (anakinra), Cimzia (certolizumab), Simponi (golimumab), Orencia SQ (abatacept). All of these medications are given by subcutaneous injection (under the skin) with the exception of Amevive, which is given intramuscularly.

NOTE: Remicade (infliximab), Orencia (abatacept), and Rituxan (rituximab), which are intravenously-administered medications used to treat many of the same conditions, are covered by TRICARE under the medical rather than the pharmacy benefit.

Background – After evaluating the relative clinical and cost effectiveness of these agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary under the Uniform Formulary. This recommendation has been approved by the Director, TMA.

- Enbrel (etanercept)
- Kineret (anakinra)
- Cimzia (certolizumab)
- Simponi (golimumab)
- Orencia SQ (abatacept)

Patients currently using a nonformulary agent may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.

2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

3. Quantity and/or days supply limits apply to Enbrel, Humira, Kineret, Cimzia, Simponi, and Orencia SQ. No more than a 4-week supply will be dispensed at any one time at retail network pharmacies (no multiple fills for multiple cost shares); no more than a 6- to 8-week supply will be dispensed at any one time at the TMOP. Usual program limits apply to Raptiva and Amevive. Please see the [Formulary Search Tool](#) for specific limits.

4. Amevive, which is given via intramuscular injection, is not available at the TMOP.

5. Medications in this class are given for a number of different rheumatological, dermatological, and gastrointestinal conditions. Not all drugs are FDA-approved (or effective) for all conditions. Three of the

medications in this class have only one FDA-approved indication (Kineret and Orencia SQ for rheumatoid arthritis and Raptiva and Amevive for plaque psoriasis).

6. The medications in this class with multiple FDA-approved indications are Enbrel, Humira, Cimzia and Simponi. Enbrel and Humira are FDA-approved for rheumatoid arthritis, moderate to severe chronic plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. Enbrel has an FDA-approved indication for juvenile rheumatoid arthritis, which Humira lacks. Humira has FDA-approved indications for Crohn's disease and ulcerative colitis, which Enbrel lacks. Because of the similarity of Enbrel and Humira with regard to mechanism of action and overlap among FDA-approved indications, Humira is considered to be the most reasonable formulary alternative to Enbrel for those conditions in which both are FDA-approved. Humira is also considered to be the most reasonable formulary alternative for treating rheumatoid arthritis.

Medical Necessity Criteria for TIBs

The non-formulary cost share for the non-formulary TIBs **Enbrel, Kineret, Cimzia, Simponi, and Orencia SQ** may be reduced to the formulary cost share if the patient meets ANY of the following criteria:

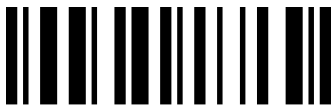
1. Use of Humira is contraindicated.
2. The patient has experienced or is likely to experience significant adverse effects from Humira.
3. Use of Humira has resulted or is likely to result in therapeutic failure.
4. The patient previously responded to a non-formulary agent and changing to Humira would incur unacceptable risk.
5. For Orencia SQ, the patient is currently receiving Orencia IV and is switching to Orencia SQ.

Criteria approved through the DOD P&T Committee process August 2012

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a component of the [Military Health System](#)
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TRICARE Pharmacy Program Medical Necessity Form for
Targeted Immunomodulatory Biologics (TIBs) –
Cimzia, Enbrel, Kineret, Orencia SQ, Simponi



5528

This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- The formulary medication in this drug class (the Targeted Immunomodulatory Biologics) is Humira. **Cimzia, Enbrel, Kineret, Orencia SQ, and Simponi are non-formulary, but available to most beneficiaries at the non-formulary cost share.** NOTE: Remicade, Orencia IV, and Rituxan, which are given intravenously, are covered under the medical benefit.
- You do **NOT** need to complete this form in order for non-active duty beneficiaries to obtain the non-formulary medication at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of the non-formulary medication instead of a formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- TRICARE will not cover a non-formulary medication for Active duty service members unless it is determined to be medically necessary instead of a formulary medication. If a non-formulary medication is determined to be medically necessary, it will be available to Active duty service members at no cost share.
- Note: Medications in this class require prior authorization before they will be covered by TRICARE for a patient newly starting on treatment. This form does NOT fulfill prior authorization requirements. Please see: http://pec.ha.osd.mil/forms_criteria.php for more information.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">• The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477• The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">• Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">○ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.○ The non-formulary medication is determined to be medically necessary.• Please contact your local MTF for more information. There are no cost shares at MTFs.

Step 1 Please complete patient and physician information (please print):

Patient Name:	_____	Physician Name:	_____
Address:	_____	Address:	_____
Sponsor ID #	_____	Phone #:	_____
Date of Birth:	_____	Secure Fax #:	_____

Step 2

1. Please indicate which medication is being requested: _____
2. Please explain why the patient cannot be treated with the formulary medication Humira. Circle a reason code if applicable. You **MUST** supply a specific written clinical explanation as to why Humira would be unacceptable.

Formulary Medication	Reason	Clinical Explanation
Humira (adalimumab)	1 2 3 4 5	

1. Use of Humira is contraindicated.
2. The patient has experienced significant adverse effects from Humira.
3. Use of Humira has resulted in therapeutic failure.
4. The patient previously responded to a non-formulary agent and changing to Humira would incur unacceptable risk.
5. **For Orencia SQ request only** - the patient is currently receiving Orencia IV and is switching to Orencia SQ.

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

3

Prescriber Signature

Date